

MAR | | 2004

Food and Drug Administration College Park, MD 20740

2717 '04 APR 23 31:58

James H. Skiles, Esq.
Vice President and General Counsel
Grocery Manufacturers of America
Second Floor
2401 Pennsylvania Avenue N.W.
Washington, DC 20037

Re: Nutrient Descriptor Claims for the Carbohydrate Content of Food (Docket No. 2004P-0110)

Dear Mr. Skiles:

This letter is in reference to the nutrient content claim petition that the Food and Drug Administration (FDA) received on February 3, 2004, pursuant to Section 403(r)(4) of the Federal Food Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. 343(r)(4)) with respect to certain claims about the carbohydrate content of foods.

We have completed our initial review of this petition. Today we are filing it in accordance with Section 403(r)(4)(A)(i) of the FFD&C Act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.69(m)(3). FDA will notify you by letter, within 90 days of filing your petition, either that a proposed regulation to provide for the requested use of the health claims will be published in the Federal Register, or that your petition is being denied. If FDA does not take one of the aforementioned actions within 90 days of the date of filing, the petition is deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner. We have calculated this date to be June 9, 2004.

2004P-0110

LET 1

Page 2 - Mr. James H. Skiles, Esq.

Please feel free to contact Ritu Nalubola at 301-436-2371 if you have questions concerning this petition.

Sincerely yours,

Laura M. Tarantino, Ph.D.
Acting Director

Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety

and Applied Nutrition